Remarks

Claims 1-23 are presently pending in the subject application.

Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

The specification has been amended herein to address the Examiner's objection to the specification, as explained below, and to correct an obvious error at page 4, lines 18-20, where Applicant mistakenly indicated that polynucleotide probes of the present invention have a net "positive" charge as opposed to a net "negative" charge. This error is clear from the specification, where it is taught, *inter alia*, that the probes of the present invention are negatively charged (*see* specification at page 30, lines 1-5) and may consist entirely of DNA or RNA (*see* specification at page 4, lines 20-23). *See* MPEP § 2163.07.II at 2100-177 (8th ed., Rev. Feb. 2003) ("An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).")

Claim 12 has been amended herein to specify that the polynucleotide probe is in solution and negatively charged and that the polycationic polymer is water soluble. Support for these amendments can be found in the specification at, for example, page 6, lines 27-28 ("water soluble"), page 16, lines 18-20 ("in solution"), and page 30, lines 1-5 ("negatively charged").

Objections to the Specification

The Examiner objects that Applicant's use of the trademark "TRITON X-100" is not accompanied by the generic terminology associated with this mark. Accordingly, Applicant has amended the specification herein to indicate that the TRITON® X-100 detergent is octoxynol. However, since Applicant has properly acknowledged that the term "TRITON X-100" is a trademark in the specification, it is unclear why the Examiner admonishes that "every effort [should be] made to prevent their use in any manner, which might adversely affect their validity as trademarks."

The Examiner states that the specification contains numerous bibliographic citations, but does not include any statement that the cited documents have been incorporated by reference. In response, Applicant directs the Examiner's attention to the paragraph 1, lines 16-23, which includes an appropriate incorporation statement for each reference identified in the specification. While the Examiner cautions that an incorporation by reference should identify the specific portions of the referenced document being relied upon, Applicant's incorporation statement clearly manifests a belief that, unless otherwise indicated, the entirety of each of the references being incorporated is relevant to the disclosed invention. For example, claim 23 specifies that the kit of claim 1 further comprises one or more amplification primers useful in amplifying a target nucleic acid sequence. Sections of the specification appearing at page 3, lines 7-12, page 6, lines 16-25, and page 37, line 26 *et seq.* disclose a number of references dedicated in their entireties to describing the identification, synthesis and use of amplification primers in a variety of amplification methods. Therefore, it is clear that the incorporations of these references cannot be limited to any particular sections of these references. Likewise, where Applicant intended a more limited incorporation, it is so indicated in the specification, as appears, for example, at page 23, lines 23-24 of the specification. Accordingly, Applicant submits that the references identified in the specification are properly incorporated by reference and may be used to satisfy any of the requirements of 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C. § 112

Claims 1-23 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as failing to satisfy the written description requirement. In support of this rejection, the Examiner contends that the claims cover any nucleic acid probe that will hybridize to any target nucleic acid, while the accompanying sequence listing only identifies three oligonucleotides. But, since the novelty of the claimed invention does not lie in the particular probe sequence selected, as long as the probe is negatively charged, the disclosure of additional probe sequences should not be required. Moreover, Applicant has provided very detailed descriptions of polynucleotide probes contemplated by the claimed invention at, for example, page 4, line 18 *et seq.*, page 10, line 8 *et seq.*, page 13, line

3 *et seq.*, and page 19, line 22 *et seq.* of the specification. *See* MPEP § 2163.I.A. at 2100-166 (8th ed., Rev. 2, May 2004) ("the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims") (citation omitted). Thus, Applicant submits that the claims are supported by an adequate written description and, therefore, withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103

Claims 1-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over International Publication No. WO 97/43450 (Cronin *et al.*) in view of U.S. Patent No. 5,200,314 (Urdea). Applicant respectfully traverses this rejection for the reasons that follow.

Cronin is cited by the Examiner for disclosing a method by which hybridization reactions are performed using polylysine. While conceding that Cronin does not teach packaging the reactants in kit form, the Examiner contends that Urdea provides the requisite motivation for compiling the reagents necessary to perform a hybridization reaction in a kit. Based on this combination of teachings, the Examiner argues that it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the reagents and guidance of Cronin for commercialization by providing the reagents in a kit, such as that disclosed by Urdea.

Applicant first observes that the Examiner's basis for this rejection overlooks an element that is present in all presently pending claims, which is the requirement that the kit include a dissociating reagent for dissociating the polycationic polymer from the polynucleotide probe and the target nucleic acid in the sample. (The Examiner's rejection also ignores many limitations set forth in the dependent claims.) *See* MPEP § 2143.03 at 2100-133 (8th ed., Rev. 2, May 2004) ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.") (citation omitted). Second, the amended claims provide that the claimed polynucleotide probe is "in solution," which is defined in the specification to mean that the

referred to polynucleotide probe is "diffusible" as opposed to bound to a solid substrate. *See, e.g.*, the specification at page 16, lines 18-20. The probes of Cronin, on the other hand, are "surface-immobilized" oligonucleotides. *See, e.g.*, Cronin at page 3, lines 15-16. Thus, Applicant submits that the claimed kits are fully patentable in view of the teachings of Cronin and Urdea, considered alone or in combination. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicant submits that the application is now in condition for allowance and early notice to that effect is hereby respectfully requested.

No fee is believed due in connection with this Reply. If Applicant is mistaken, please charge the amount due to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Certificate of Transmission

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Respectfully submitted,

Date: June 13, 2005

By: _____

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